IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

----------X

ANNIE TUMMINO, *et al.*,

Plaintiffs,

CV-05-0366 (ERK/VVP)

v.

MARGARET HAMBURG, *et al.*,

Defendants.

----------X

PLAINTIFFS' POST-REMAND MOTION FOR PRELIMINARY INJUNCTION AND SUMMARY JUDGMENT

Plaintiffs respectfully move this Court to issue a preliminary injunction and grant summary judgment in Plaintiffs' favor. This motion is supported by the following documents filed herewith: the memorandum of law filed in support of this motion, and the declarations of Cynthia C. Harper, Ph.D.; Mary K. Pendergast, J.D., LL.M.; Elizabeth G. Raymond, M.D., M.P.H.; and Tracey Wilkinson, M.D., M.P.H.

Plaintiffs seek a preliminary injunction pursuant to Rule 65 of the Federal Rules of Civil Procedure directing Defendants to permit, within 30 days, the drug sponsors of Plan B One-Step, Plan B, Next Choice, Perrigo R and D's Levonorgestrel Tablets, and any drug eligible for filing an abbreviated new drug application because of its equivalence to Plan B or Plan B One-Step, to make the above-referenced products available over-the-counter without age or point of sale restrictions. Given the harms that the FDA's bad faith tactics have imposed upon women for

over ten years, Plaintiffs respectfully submit that this Court issue such an order immediately. A preliminary injunction is warranted because Plaintiffs can show a clear or substantial likelihood of success on the merits; that they face irreparable harm absent injunctive relief; and that the public's interest weighs in favor of granting an injunction. *Red Earth LLC v. United States*, 657 F.3d 138, 143 (2d Cir. 2011); *Doninger v. Niehoff*, 527 F.3d 41, 47 (2d Cir. 2008).

Plaintiffs move this Court pursuant to Rule 56 of the Federal Rules of Civil Procedure, for summary judgment on the cause of action stated in their proposed Supplemental Complaint. Summary judgment is appropriate because there are no genuine disputes of material fact and Plaintiffs are entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). To the extent the FDA contests any of the facts presented in support of Plaintiffs' underlying motion, Plaintiffs hereby move to reopen discovery immediately. Plaintiffs seek a permanent injunction directing Defendants to permit, within 30 days, the drug sponsors of Plan B One-Step, Plan B, Next Choice, Perrigo R and D's Levonorgestrel Tablets, and any drug eligible for filing an abbreviated new drug application because of its equivalence to Plan B or Plan B One-Step, to make the above-referenced products available over-the-counter without age or point of sale restrictions.

Dated: February 8, 2012

Respectfully submitted,

/s/ *Suzanne Novak*

SUZANNE NOVAK
JANET CREPPS*
Center for Reproductive Rights
120 Wall Street, 14th Floor
New York, NY 10005
(917) 637-3600

Attorneys for all Plaintiffs

ANDREA COSTELLO*
Florida Institutional Legal Services

14260 W. Newberry Road, #412
Newberry, FL 32669
(352) 375-2494 x1012

Attorneys for Plaintiffs
Tummino, Mahoney, Giardina,
Mangan, Seguin, Tinney, Brown
Churchill and Hunt

**Admitted pro hac vice*

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

----------X

ANNIE TUMMINO, *et al.*,

Plaintiffs,

CV-05-0366 (ERK/VVP)

v.

MARGARET HAMBURG, *et al.*,

Defendants.

----------X

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' POST-REMAND MOTION FOR PRELIMINARY INJUNCTION AND SUMMARY JUDGMENT

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

FEDERAL COURT CASES **Page**

FEDERAL STATUTES AND RULES

FOOD AND DRUG ADMINISTRATION PUBLICATIONS

OTHER AUTHORITIES

INTRODUCTION

Over the course of a decade, the FDA has persistently denied women unrestricted over-the-counter ("OTC") access to emergency contraception, despite overwhelming evidence that it is safe and effective for self-administration and otherwise meets the standard for unrestricted OTC status. The FDA's treatment of emergency contraception has departed significantly from its normal practices without any justifiable explanation. Its ten years of delay and obfuscation has made this a long tale, but the charge is simple: The FDA has failed to meet its obligations to the public to make medical decisions based on science, letting politics prevail instead.

Three years ago, this Court vacated the FDA's denial of the Citizen Petition seeking OTC status for levonorgestrel-based emergency contraception because the FDA had acted arbitrarily and capriciously and issued the denial in bad faith. Plaintiffs are entitled to a preliminary injunction and summary judgment because, as described herein, there can be no dispute that following remand, the FDA continued its bad faith and arbitrary and capricious actions, causing Plaintiffs and the public to continue to suffer significant harm. Indeed, the FDA's actions following remand mirror the very actions that supported this Court's original findings of bad faith and arbitrary and capricious behavior, including an unprecedented order by the Health and Human Services Secretary directing the FDA to deny an OTC request for emergency contraception.[1]

[1] For the purposes of this Memorandum, Health and Human Services Secretary Kathleen Sebelius is considered to be part of the FDA because she has asserted authority to overrule an FDA drug approval decision as the person "responsible for executing" the Federal Food, Drug, and Cosmetic Act ("FDCA"). Memorandum from Kathleen Sebelius to Margaret A. Hamburg (Dec. 7, 2011) (ECF No. 339-1 at 3).

FACTS

A. Emergency Contraception Products

Emergency contraception is used to reduce the risk of unwanted pregnancy after sexual intercourse. There are currently multiple brands of emergency contraception that include levonorgestrel as the sole active ingredient (collectively, "EC"). Levonorgestrel "does not have any known serious or long-term side effects." *Tummino v. Torti*, 603 F. Supp. 2d 519, 522 (E.D.N.Y. 2009); Raymond Decl. ¶ 8. EC is highly effective if taken within 72 hours of sexual intercourse, but its effectiveness is greatest if it is taken within 24 hours. *Tummino*, 603 F. Supp. 2d at 522.

In 1999, the FDA approved the first levonorgestrel-only drug to be marketed as emergency contraception, Plan B. Plan B consists of two pills, each with 0.75 mg of levonorgestrel, with the label instructing them to be taken twelve hours apart. There are currently two generic two-pill levonorgestrel products, Next Choice and a generic made by Perrigo R and D. The manufacturer of Plan B, no longer markets Plan B; since 2009, it has marketed Plan B One-Step, which is a single pill with 1.5 mg of levonorgestrel. An emergency contraception product that has a different active ingredient, ulipristal acetate, was approved by the FDA in 2010 and is marketed in the U.S. under the name ella; ella is not at issue in this litigation.

B. Over–the-Counter Availability of Drugs

By statute, the default status for drugs is OTC, *see* Pls.' Fifth Amend. Compl. Ex. U (ECF No. 207 at 32),—a drug like an EC product shall be limited to prescription status only when "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, [it] is not safe for use except under the supervision of

a practitioner licensed by law to administer such drug." 21 U.S.C. § 353(b)(1)(A). A drug is suitable for OTC use when it is found to be safe and effective for self-administration and when its labeling clearly provides directions for safe use and warnings regarding unsafe use, side effects, and adverse reactions. *See* 21 C.F.R. § 310.200(b); § 330.10(a)(4); *Tummino*, 603 F. Supp. 2d at 525. As this Court has explained, these regulations were intended, in part, "to relieve retail pharmacists and the public from burdensome and unnecessary restrictions on the dispensing of drugs that are safe for use without the supervision of a physician." *Tummino*, 603 F. Supp. 2d at 525.

A drug can be switched from prescription to OTC status if the drug sponsor or "any interested person" requests such a switch, and the FDA approves. *Id.* at 525. In addition, the FDA can switch a drug from prescription to OTC status without being asked to do so. Declaration of Mark K. Pendergast, J.D., LL.M. (hereinafter "Pendergast Decl.") ¶¶ 6-7, 16, 26-27. A determination of whether a switch to OTC of a drug like EC is appropriate is normally handled at the Office Director level within the FDA and would not require approval or sign-off by a higher level official. *Tummino*, 603 F. Supp. 2d at 529. It certainly would not require the approval of anyone as high up as the Commissioner of Food and Drugs or the Secretary of Health and Human Services.[2]

There are no specific documents or information that must be submitted with an OTC switch request. Actual use and label comprehension studies are sometimes, but not always, submitted with such requests. Letter from Janet Woodcock, Dir., Center for Drug Evaluation and Research ("CDER") at 4 (Dec. 12, 2011) (denying Citizen Petition) (ECF No. 341-1)

[2] Within the relevant branches of the hierarchy of the FDA, there are Office Directors (at, *e.g.*, the Office of Drug Evaluation V); above them is the Director of the Center for Drug Evaluation and Research ("CDER"); above her is the Commissioner of Food and Drugs; and above her is the Secretary of Health and Human Services at the Cabinet level.

(hereinafter "Cit. Pet. Denial Ltr. Dec. 12, 2011"); Pendergast Decl. ¶¶ 23-24. The purpose of an actual use study is to simulate the OTC use of a product and predict if a drug will be used correctly, safely, and effectively in the OTC setting by the target population of the product. Declaration of Cynthia C. Harper, Ph. D (hereinafter "Harper Decl.") ¶ 5. The FDA typically does not require subjects of any particular age to be included in actual use studies. *Id.* ¶¶ 9, 20. Rather, as this Court noted, "the Agency has a long history of extrapolating findings from clinical trials in older patients to adolescents." *Tummino*, 603 F. Supp. 2d at 527.[3]

Label comprehension studies for OTC drugs are a relatively new phenomenon and are not always required for an OTC switch. Ctr. For Drug Evaluation & Research, U.S. Food & Drug Admin., Guidance for Industry: Label Comprehension Studies for Nonprescription Drug Products (August 2010) (hereinafter "FDA Label Comprehension Study Guidance"), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM143834.pdf; Pendergast Decl. ¶¶ 24. As the evidence before this Court demonstrates, the FDA has approved numerous OTC switches without requiring label comprehension studies. Pls.' Mem. in Supp. of Summ. J. Ex. E (ECF No. 235-10 at 18-19). And the FDA has approved OTC switches for numerous prescription drugs and classes of prescription drugs whose directions for approved use are far more complicated than the directions for Plan B. *Id.* at 44 (citing Jenkins Dep. 101:5-18); Declaration of Elizabeth G. Raymond, M.D., M.P.H. (hereinafter "Raymond Decl.") ¶ 10; Pendergast Decl. ¶ 21, 24.

The purpose of a label comprehension study is not to test the ability of consumers to use the product properly. Rather, it is to determine whether there are "areas on the label that would

[3] *See also id.* at 532 (noting that this practice was incorporated into the Pediatric Research and Equity Act); 21 U.S.C. § 355c(a)(2)(B)(ii) ("A study may not be needed in each pediatric age group if data from one age group can be extrapolated to another age group.").

benefit from clearer or simpler presentation of important consumer information." FDA Label Comprehension Study Guidance at 1; *see also* Cit. Pet. Denial Ltr. Dec. 12, 2011 at 4 n.2. Label comprehension studies do not provide information regarding product safety. FDA Label Comprehension Study Guidance at 1.

For the occasions when it does require label comprehension studies, the FDA provides written guidance regarding how such studies should be designed and conducted, highlighting important considerations. *Id.* at 2. One of those considerations is enrolling a demographically diverse population with varying levels of literacy. *Id.* at 3. The FDA Label Comprehension Study Guidance provides substantial guidance regarding enrolling an adequate number of subjects with low literacy skills. *Id.* at 5. It makes no mention, however, of needing to enroll an adequate number of subjects for any particular age and explains that education level is not a reliable substitute for literacy testing. *Id.*

Indeed, it is unusual for actual use and label comprehension studies to include persons under 18. Pls.' Mem. in Supp. of Summ. J. Ex. E (ECF No. 235-10 at 18-19) (showing that, other than Plan B, only two of eight OTC switches between 2001 and 2005 were supported by actual use studies that included data on individuals under 18, and none by label comprehension studies with such data). This is not surprising because, as noted above, the FDA usually extrapolates data from adults to the pediatric population. Moreover, when the agency has not been confident of the applicability of manufacturers' studies in OTC switches to younger consumers, it has required a label warning, rather than an age restriction or outright denial. Pls.' Mem. in Supp. of Summ. J. 71 (citing Jenkins Dep. 91:11-19, 113:7-16, 118:13-119:9) (ECF No. 236).

The FDA has approved OTC switches for numerous prescription drugs and classes of prescription drugs that could cause more severe side effects even when they are used according to approved directions, than could the correct, or even incorrect, use of Plan B. *Id.* at 43 (citing Grimes Decl. ¶ 10(E) and Houn Dep. 120:18-121:17, 127:2-128:12). Many of those unrestricted OTC drugs pose special risks for certain populations, including certain age groups. *Id.* (citing Jordan Decl. ¶ 21; Jenkins Dep. 113:2-16). For example, aspirin is not recommended for use by children or adolescents with viral infections, because of the risk of developing Reye's Syndrome – a potentially fatal illness. *Id.* at 44 (citing Jordan Decl. ¶ 21). Nevertheless, aspirin is widely available for unrestricted purchase. FDA, Orange Book, http://www.accessdata.fda.gov/scripts/cder/ob/docs/queryai.cfm (search "OTC" products by Active ingredient "Asprin") (last visited Feb. 7, 2012). And many products are readily available OTC even though they are known to be abused both by minors and adults, including aspirin, ibuprofen, and acetaminophen, which cause hundreds of deaths each year in the U.S. Pls.' Mem. in Supp. of Summ. J. 42 (citing Tummino 30757-58, 31086; Jordan Decl. ¶ 21; Grimes Decl. ¶ 10(E)); Raymond Decl. ¶ 8.

C. The FDA's Actions Regarding EC Prior to the Instant Lawsuit

As previously explained by this Court, the history of the FDA's treatment of emergency contraception is one of unwarranted delays, denials, and departures from normal procedures. *Tummino,* 603 F. Supp. 2d at 526-38; *see also* Pls.' Mem. in Supp. of Summ. J. 18-44. In 2001, Plaintiff Association of Reproductive Health Professionals and sixty-five other organizations filed a Citizen Petition asking the FDA to switch Plan B and all similar emergency contraceptives from prescription-only to over-the-counter ("OTC") status. *Tummino,* 603 F. Supp. 2d at 526. The FDA delayed a decision on the Citizen Petition for years. During the same

period, the manufacturer of Plan B submitted a series of supplemental new drug applications ("SNDAs") in an attempt to have that drug switched to OTC status. The FDA treated these two processes as intertwined, "acknowledg[ing] that the issues presented by the SNDAs and the Citizen Petition were one and the same." *Id.* at 537; *see also id.* at 543. The Citizen Petition was denied in 2006; in the denial the FDA stated that it "expected that some or all of the issues . . . raised in [the] petition would be resolved in the then-anticipated SNDA proceeding." *Id.* at 543.

In the SNDA proceedings, the FDA repeatedly moved the goalposts, requiring multiple applications from the drug sponsor. The FDA denied the first SNDA, informing the sponsor that "it needed to provide more information on safe use by women under 16, or more information in support of a dual marketing plan that would sell Plan B as a prescription-only product to women under 16." *Id.* at 532. But from the outset, the FDA had worked with the sponsor on the design of its actual use study:

> [T]he FDA made a number of recommendations regarding the age composition of participants in a proposed actual use study and the importance of enrolling young adolescents. The sponsor indicated that it would seek to enroll at least 50 participants aged 17 years of age or younger. The FDA did not disapprove of this figure or recommend a larger number. Indeed, in subsequent meetings prior to the filing of the SNDA, FDA staff assured the sponsor that the actual use study, the study the FDA considered 'pivotal' to the application, 'appear[ed] to be adequate for filing.'

Tummino, 603 F. Supp. 2d at 526 (internal citations omitted); *see also* Raymond Decl. ¶¶ 25, 29. "Moreover, as early as April 2002, the FDA informed the Plan B sponsor that results from trials in the adult population could be extrapolated to the postmenarcheal pediatric population." *Tummino*, 603 F. Supp. 2d at 526-27.

After the FDA denied its initial SNDA, the sponsor submitted an amended SNDA formally proposing a dual marketing plan that would make Plan B OTC for consumers 16 and older, an idea that had been informally proposed at the FDA's urging. *Id.* at 531, 533. But the

FDA ultimately rejected this application too, claiming in a letter from then-Acting Commissioner Andrew von Eschenbach that there was not enough data concerning women under 18 and demanding that the sponsor amend the SNDA to request OTC status for women 18 and older. *Id.* at 535.

The sponsor submitted a third SNDA in response to the FDA's new demand, this time proposing a marketing regime that would require women under 18 to have a prescription. *Id.* at 536. The FDA eventually partially approved Plan B for OTC status but with an unprecedented regime requiring that women under 18 obtain a prescription for the product, that Plan B be sold only in pharmacies and health clinics, that the drug be kept behind the counter, and that consumers present government-issued identification to obtain it (the "BTC regime"). *See* Press Release, FDA Approves Over-the-Counter Access for Plan B for Women 18 and Older; Prescription Remains Required for Those 17 and Under (Aug. 24, 2006) (ECF No. 248-4 at 24). Today, Plan B One-Step and all of the two-pill EC products are governed by the BTC regime, except that a prescription is required for those under 17, rather than under 18.

The FDA, however, has had sufficient evidence to make EC available OTC for women of all ages since it began consideration of the matter. *See Tummino*, 603 F. Supp. 2d at 526 (quoting FDA statement that Citizen Petition "clearly outlines . . . how Plan B[ ] meet[s] all the criteria for OTC availability"); *see also id.* at 531 (stating, when discussing first SNDA, that "FDA scientific review staff uniformly and strongly supported approval of Plan B for OTC sales without age or point-of-sale restrictions"). The FDA reviewers who concluded that unrestricted OTC status for women of all ages was appropriate relied on actual use data, including data on adolescents. *Id.* at 530 ("Of the more than 11,000 enrollees in [the studies submitted with the initial SNDA], just over 1,000 were under 16, nearly 2,000 were 17 or younger, and at least 200

of the subjects in one study were aged 13 to 15."). In addition, the sponsor conducted two label comprehension studies—one focused on women 12 to 17 years old—that did not reveal any problems with participants' ability to understand the proposed label for Plan B. Raymond Decl. ¶¶ 15-23, 30-35. The data showed that there was no scientific basis for a distinction between adults and adolescents. *Id.* ¶¶ 20-28 (describing, *inter alia*, actual use study that included teens and found that "the minors in the study were not substantially more likely than others to use the product in a contraindicated or incorrect manner"); Harper Decl. ¶ 6.

The Government Accountability Office ("GAO") investigated the process leading to the FDA's denial of the first SNDA. *Tummino*, 603 F. Supp. 2d at 537; Pls.' Mem. in Supp. of Summ. J. Ex. B (ECF No. 235-6) (hereinafter "GAO Report"). The GAO Report found several irregularities, including novel justifications about adolescents' cognitive development, which this Court found significant in holding the FDA's actions with respect to Plan B were arbitrary and capricious. *See Tummino*, 603 F. Supp. 2d at 547; GAO Report 5-6.

D. Barriers Created by the Dual Marketing Regime

The BTC regime currently applies to all levonorgestrel-based EC products. There is mounting evidence that this unprecedented regime undermines the very reason OTC access was introduced: "to relieve retail pharmacists and the public from burdensome and unnecessary restrictions on the dispensing of drugs that are safe for use without the supervision of a physician." *Id.* at 525 (internal citations omitted). The restrictions often impose significant barriers on access to EC even for those consumers who are supposed to be able to purchase it OTC.

For example, permitting EC to be available only at pharmacies and health clinics imposes practical obstacles to access. Some consumers do not live near such businesses. *See* Declaration

of Tracy Wilkinson, M.D., M.P.H. (hereinafter "Wilkinson Decl.") ¶ 9; Raymond Decl. ¶ 38. Because pharmacies usually have limited hours, consumers who attempt to buy EC at certain times can face significant delay. *See* Wilkinson Decl. ¶ 9 (stating that less that 5% of pharmacies surveyed were open 24 hours); Raymond Decl. ¶ 38; Pls.' Mem. in Supp. of Summ. J. 13. Delay decreases the effectiveness of the drug. *See* Wilkinson Decl. ¶ 5, 10.

The requirement that consumers show government-issued identification also creates a potentially insurmountable barrier for the many consumers who do not have such identification. *See* Raymond Decl. ¶ 38; Wilkinson Decl. ¶ 9. This rule also has the effect of requiring consumers to reveal their identity in order to purchase a product, which implicates privacy concerns. *See* Pls.' Mem. in Supp. of Summ. J. Ex. C (Grimes Decl. ¶ 12) (ECF No. 235-7 at 21).

Moreover, the BTC regime is complicated and unique, and many pharmacists implement it incorrectly in ways that block consumers' access. A recent study published in the Journal of the American Medical Association found that a 17-year-old attempting to buy EC faces an approximately one-in-five chance of being told incorrectly that she cannot obtain the drug without a prescription because of her age. *See* Wilkinson Decl. ¶ 8. And pharmacists are more likely to misinform young women about the age cutoff in low-income neighborhoods, perpetuating a pattern of poor access to health care for low-income populations. *Id.*

The cumulative effect of the barriers erected by the BTC regime undoubtedly prevent some women from accessing the drug in the short time window in which it is effective, thereby exposing them to an increased risk of unwanted pregnancy and frustrating the very purpose of OTC access. *Id.* ¶ 10; Harper Decl. ¶¶ 21; *cf. id.* ¶ 7. As a public health issue, the adverse effect of the dual-label status in limiting access to emergency contraception is more detrimental to

adults than younger patients because the vast majority of women who need emergency contraception are adults. Raymond Decl. ¶ 38.

E. This Lawsuit and the Court's March 2009 Order

In 2005, while the FDA was creating new hoops for the Plan B drug sponsor to jump through, Plaintiffs filed this lawsuit asserting that the FDA's actions with respect to the Citizen Petition and Plan B were arbitrary and capricious and exceeded the agency's statutory authority and that those actions violated the U.S. Constitution. Plaintiffs filed a motion for summary judgment on March 31, 2007, which this Court granted in March 2009. The Court explained that "the gravamen of plaintiffs' claims is that the FDA's decisions regarding Plan B—on the Citizen Petition and the SNDAs—were arbitrary and capricious because they were not the result of reasoned and good faith agency decision-making" and concluded that "Plaintiffs are right." *Tummino*, 603 F. Supp. 2d at 523. This Court found that the FDA's decisions on Plan B took political considerations into account, had implausible justifications, and departed in significant ways from the agency's normal procedures for requested OTC switches. *Id.* at 523-24**.** Notable departures included: FDA upper management wresting control over the decision-making process from staff that normally would issue the final decision; the agency making a decision to reject the first Plan B OTC SNDA before the scientific reviews had been completed; the agency making a decision contrary to the recommendation of the scientific review staff; and the agency's insistence on additional data for adolescents when data on adolescents already existed and there was a long agency history of extrapolating adult data to adolescents. *Id.* at 547-48.

The FDA's bad faith actions are exemplified in this Court's finding that the Commissioner of Food and Drugs von Eschenbach's "concern about the inadequacy of data available for young adolescents" was motivated by political pressure from the White House, and

that "the Commissioner transmitted this pressure down the chain of command at the FDA: pressuring Dr. Galson not to approve over-the-counter use of Plan B without age restriction." *Id.* at 546. Dr. Galson, Acting Director of the Center for Drug Evaluation and Research, twice concluded that Plan B should not be made available to adolescents OTC. "Central to this decision" was Dr. Galson's conclusion that "it was invalid to extrapolate data from older to younger adolescents in this case" because of the diminished capacity of adolescents to make rational decisions and the "large developmental differences" between early- and mid-adolescence. *Id.* at 532-33, 538. But, as this Court explained, "the GAO concluded that 'the rationale for [Dr. Galson's] decision was novel and did not follow FDA's traditional practices.'" *Id.* at 537-38. The GAO report noted that "[t]he Acting Director [Galson] acknowledged to GAO that considering adolescents' cognitive development as a rationale for a not-approvable decision was unprecedented for an OTC application." GAO Report 5-6. And this Court confirmed that there was unrebutted evidence that the FDA's focus on adolescent cognitive development in its evaluation of Plan B as an OTC drug stemmed from political pressure rather than permissible health and safety concerns. *Tummino*, 603 F. Supp. 2d at 537-38.[4] Indeed, the Court noted that Dr. Galson reached his conclusions regarding insufficient data on teens for one of the switch applications while unaware that additional studies submitted in support of the OTC switch, including eight behavioral studies, *did* contain data for adolescent women. *Id.* at 530.

Based on these findings, the Court ordered the FDA to, within 30 days of its Order, permit the Plan B drug sponsor "to make Plan B available to 17 year olds without a prescription,

[4] As this Court noted, Dr. Jenkins, Director of the Office of New Drugs, explained that there was no unique safety concern for the drug in women under age 16 and that any concerns regarding the "developmental differences between adolescents and older women" were "more applicable to the ability of adolescents to make reasoned decisions about engaging in sexual intercourse, not their ability to understand how to use Plan B safely and effectively as an emergency contraceptive should they engage in unprotected sexual intercourse." *Tummino*, 603 F. Supp. 2d at 533-34 (internal citations omitted).

under the same conditions as Plan B is now available to women over the age of 18." *Id.* at 550. It further ordered that "the FDA's denial of the Citizen Petition is vacated and the matter is remanded to the FDA for reconsideration of whether to approve Plan B for over-the-counter status without age or point-of-sale restrictions." *Id.* at 524. It explained that "remand to the FDA for it to reconsider its denial of the Citizen Petition is the appropriate remedy." *Id.* at 549.

F. The FDA's Failure to Comply with the Court's Order for Years

Despite this Court's Order requiring the FDA to reconsider the Citizen Petition, *id.* at 549-50, for over two and a half years the agency refused to take any steps to do so. Indeed, the FDA acknowledged that the first step in reviewing the Citizen Petition would be to determine whether sufficient data exist to support an OTC switch, and that it had no intention of taking that step. Def.'s Mem. in Opp'n to Contempt 9-10, 22 (ECF No. 315). The FDA informed Plaintiffs that it believed that "the best way for FDA to comply with the court's order is to review a supplemental new drug application expected to be submitted by the sponsor of Plan B One Step" for OTC access for all ages. Letter from F. Franklin Amanat (Aug. 13, 2010) (ECF No. 307-3 at 18). The FDA's admission that it planned to indefinitely ignore the Court's Order to reconsider the Citizen Petition prompted Plaintiffs to move for contempt.

In letters to Plaintiffs and filings regarding Plaintiffs' contempt motion, the FDA argued out of both sides of its mouth: It contended that, on the one hand, it could satisfy the Court's Order by considering the Plan B One-Step SNDA, essentially arguing that the one-pill and two-pill versions of the drugs are equivalent and interchangeable for purposes of the Court's Order. Def.'s Mem. in Opp'n to Contempt 14-17. But in the next breath it also argued that the Citizen Petition "does not cover Plan B One-Step," thus indicating that a grant of the Plan B One-Step

SNDA would not result in the relief sought by the Citizen Petition. *See* Def.'s Reply to Pls.' Responses to Court Order 2 (ECF No. 333).

G. The Plan B One-Step SNDA

In February of 2011, the Plan B One-Step sponsor submitted an SNDA seeking to make Plan B One-Step OTC for all ages. *See* Supplemental Declaration of Jane A. Axelrad (hereinafter "Axelrad Supp. Decl.") ¶ 7 (ECF. No. 322-1). In communications that began years before that submission, the FDA told the drug sponsor that the Plan B One-Step SNDA must include data regarding use by women ages 11 to 17. *See* Harper Decl. ¶¶ 8, 13, 15; Raymond Decl. ¶ 30. The agency insisted on data specific to teens despite: (1) the existing data from studies on the two-pill version, Plan B, that showed EC was appropriate for OTC status for women of all ages ; and (2) this Court's holding that insisting on such data was contrary to agency norms and the agency's previous treatment of EC was arbitrary and capricious. *See* Raymond Decl. ¶ 6; Harper Decl. ¶¶ 6, 8, 9; *Tummino*, 603 F. Supp. 2d at 547-48.

As with the Plan B approval process, the drug sponsor worked closely with the FDA in designing the studies regarding Plan B One-Step, making modifications at the agency's request. *See* Harper Decl. ¶¶ 10-17; Raymond Decl. ¶¶ 31-33. Although the researchers worked hard to recruit subjects in the age ranges the FDA wanted, Harper Decl. ¶¶ 15-16, they reasonably did not expect to be able to find any, or a meaningful number of, 11 and 12 year olds to include in a study on use of EC because so few 11 and 12 year olds ever use EC. Harper Decl. ¶¶ 13-14 ("An actual use study considers the way that *the target population* of a particular product will use that product. Since only rare 11 year olds might need to use emergency contraception, we would be hard-pressed to find them and include them in the actual use study."); Raymond Decl. ¶ 37; Pls.' Mem. in Supp. of Summ. J. Ex. A-1 (ECF No. 235-2 at 53) (showing only a handful

of the tens of thousands who used EC from 2002 to 2004 were 11 or younger). The studies did, however, include a sample of subjects that allowed the researchers to conclude that the target population for EC is able to correctly use EC in an OTC setting. Harper Decl. ¶ 20; Raymond Decl. ¶ 38.

The data that was submitted to the FDA in support of the Plan B One-Step SNDA confirms what the previous studies all showed—that emergency contraception is safe and effective for all women when self-administered. Harper Decl. ¶¶ 6, 19-20; Raymond Decl. ¶¶ 6, 21, 23, 27-28, 35, 38. In particular, the recent actual use study on Plan B One-Step found that teens of all ages are capable of understanding what emergency contraception is indicated for and of using it correctly when needed. Harper Decl. ¶¶ 19-20; Raymond Decl. ¶ 35.

H. Events Between December 7 and 13, 2011—Denials of the Plan B One-Step SNDA and the Citizen Petition

In the six days between December 7 and 13, 2011, the FDA denied both the Plan B One-Step SNDA and the Citizen Petition. On December 7, 2011, Dr. Margaret Hamburg, Commissioner of Food and Drugs, issued a statement regarding Plan B One-Step. In it, the Commissioner stated that CDER had completed its review of the Plan B One-Step SNDA and set forth key conclusions reached based on the data submitted to it:

> CDER determined that the product was safe and effective in adolescent females, that adolescent females understood the product was not for routine use, and that the product would not protect them against sexually transmitted diseases. Additionally, the data supported a finding that adolescent females could use Plan B One-Step properly without the intervention of a healthcare provider.

FDA, Statement from FDA Commissioner Margaret Hamburg, M.D. on Plan B One-Step (Dec. 7, 2011) (ECF No. 339-2). She stated that:

> It is our responsibility at FDA to approve drugs that are safe and effective for their intended use based on the scientific evidence. The review process used by CDER to analyze the data applied a risk/benefit assessment consistent with its

> standard drug review process. Our decision-making reflects a body of scientific findings, input from external scientific advisory committees, and data contained in the application that included studies designed specifically to address the regulatory standards for nonprescription drugs.

Id. She further explained that CDER experts agreed that Plan B One-Step had met the OTC standards and should be approved for all women of child-bearing potential and that her independent review confirmed that Plan B One-Step should be approved for OTC use without age restrictions. *Id.* That should have been the end of the story and, for any other product, would have been.

On that very same day, however, for what apparently is the first time ever, the Secretary of Health and Human Services, Kathleen Sebelius, asserted authority to overrule an FDA drug approval decision as the person "responsible for executing" the FDCA. Memorandum from Kathleen Sebelius to Margaret A. Hamburg (Dec. 7, 2011) (ECF No. 339-1 at 3); *see* Pendergast Decl. ¶ 33. She directed the FDA to deny Plan B One-Step's SNDA, stating that she "carefully considered FDA's Division Director Summary Review of Regulatory Action, dated November 30, 2011," and, that based on that review, "concluded that the data submitted for this product do not establish that prescription dispensing requirements should be eliminated for all ages." Memorandum from Kathleen Sebelius to Margaret A. Hamburg (Dec. 7, 2011) (ECF No. 339-1 at 2). She further stated that:

> the switch from prescription to over the counter for this product requires that we have enough evidence to show that those who use this medicine can understand the label and use the product appropriately. I do not believe that Teva's application met that standard. The label comprehension and actual use studies did not contain data for all ages for which this product would be available for use.

Press Release, Statement by U.S. Department of Health and Human Services Secretary Kathleen Sebelius (Dec. 7, 2011) (ECF No. 339-1 at 4). She noted that "it is commonly understood that there are significant cognitive and behavioral differences between older adolescent girls and the

youngest girls of reproductive age, which I believe are relevant to making this determination." Memorandum from Kathleen Sebelius to Margaret A. Hamburg, (Dec. 7, 2011) (ECF No. 339-1 at 2). Secretary Sebelius specifically noted that 10 percent of girls start menstruating at age 11. *Id.*

Although the FDA had previously indicated to the Court that it would indefinitely defer reconsidering or ruling on the Citizen Petition because it believed a decision on Plan B One-Step SNDA would satisfy the Court's Order, Def.'s Mem. in Opp'n to Contempt 20-24, it scurried at the eleventh hour to re-rule on the Citizen Petition before having to appear in Court on Plaintiffs' motion for contempt. The FDA issued a denial of the Citizen Petition a mere 21 hours before that oral argument.

Reading the denial, one would think that this Court never issued its 2009 Order. The FDA based the denial on the very findings that the Court had found to be infiltrated with politics, taken in bad faith, and arbitrary and capricious:

- Dr. Galson's determinations in 2005 that the Citizen Petition/Plan B files could not support an OTC switch because of insufficient data on adolescents, *see* Cit. Pet. Denial Ltr. Dec. 12, 2011 at 5; *see also id* at 7, 10;
- The lack of actual use and label comprehension studies submitted with the Citizen Petition, *id.* at 7; and
- Plaintiffs and their supporters' failure to submit additional data after the FDA re-opened the docket for the Citizen Petition following this Court's Order, *see id.* at 5-6; 10.

In the denial, the FDA contended that "the court did not reject . . . FDA's determination that neither the Citizen Petition nor the Plan B SNDA contained [adequate data demonstrating that the statutory standards were satisfied] for women under the age of 17." *Id.* at 5.

The FDA makes no pretense of having conducted an actual review and reconsideration of the Citizen Petition and Plan B's files in a fair, scientifically-based manner in accordance with

FDA norms. Rather, it drew conclusions about and denied the Citizen Petition based on its review of a separate and distinct drug application for a different product. According to the FDA:

> [a]s a scientific matter, if additional data regarding the OTC use by younger women were needed for Plan B One-Step, that type of data would also be needed for Plan B, but those Plan B One-Step studies would not be transferable to Plan B. Instead, there would need to be new studies conducted using Plan B and its labeling, because it has more complicated directions for use, raising additional questions as to label comprehension and actual use.

Id. at 2; *see also id.* at 3, 7. It concluded, as part of its consideration of the Plan B One-Step application, that such data was needed for Plan B One-Step. Then, rather than review and reconsider the Citizen Petition and Plan B files, it simply concluded that such additional data also would be necessary for it to grant the Citizen Petition. *Id.* at 9-10.

The letter explains that the FDA had determined, before Secretary Sebelius' intervention, that the totality of the Plan B One-Step application, including the new data, demonstrated that Plan B One-Step met the standards for unrestricted OTC status. *Id.* at 9. The letter further set forth the following key elements evaluated in the label comprehension study of the Plan B One-Step label:

1. Plan B One-Step is indicated for prevention of pregnancy after unprotected sex;
2. Plan B One-Step should be taken as soon as possible after sex;
3. Plan B One-Step does not prevent sexually transmitted diseases or HIV/AIDS;
4. Plan B One-Step should not be used in place of regular contraception;
5. Plan B One-Step should be taken within 72 hours after sex; and
6. Plan B One-Step should not be used by women who are already pregnant.

Id. at 8-9. It also describes the two primary objectives of the actual use study as: (1) to determine the percentage of subjects who appropriately self-selected; and, (2) to determine the proportion of subjects who correctly used Plan B One-Step under simulated OTC conditions. *Id.* at 9.

ARGUMENT

Plaintiffs are entitled to a preliminary injunction and summary judgment on their claim that the FDA's actions following remand were arbitrary and capricious in violation of 5 U.S.C. § 706(2)(A). The FDA's actions are arbitrary and capricious by any standard. Against the backdrop of the unreasonable delay and other bad faith conduct over the past ten years, however, the FDA's recent actions are nothing short of outrageous. In striking fashion, the FDA engaged in virtually the same actions, often with the same untenable rationales, that it engaged in between 2001 and 2006 and that prompted this Court to rule that the agency's actions were arbitrary and capricious and taken in bad faith. Essentially, the only differences between before and after the Court's ruling are some different actors and five additional years during which unwarranted barriers have been placed in front of women trying to access a safe, effective, and legal birth control product. *See Pub. Citizen Health Research Group v. Brock*, 823 F.2d 626, 629 (D.C. Cir. 1987) ("[W]e cannot countenance maneuvering that merely maintains a facade of good faith compliance with the law while actually achieving a result forbidden by court order.").

I. Applicable Legal Standards

A preliminary injunction is warranted when a party seeking a mandatory injunction demonstrates (1) a clear or substantial likelihood of success on the merits; (2) irreparable harm absent injunctive relief; and, (3) that the public's interest weighs in favor of granting an injunction. *Red Earth LLC v. United States*, 657 F.3d 138, 143 (2d Cir. 2011); *Doninger v. Niehoff*, 527 F.3d 41, 47 (2d Cir. 2008).

Plaintiffs are entitled to summary judgment if the pleadings, depositions, answers to interrogatories and admissions on file, together with affidavits, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.

Fed. R. Civ. P. 56(c); *Spinelli v. City of New York*, 579 F.3d 160, 166 (2d Cir. 2009). In determining whether there is a genuine issue of material fact, the court must resolve all ambiguities and draw all inferences in favor of the non-moving party. *E.g.*, *United States v. Diebold, Inc.*, 369 U.S. 654, 655 (1962) (per curiam); *GlobalNet Financial.com, Inc. v. Frank Crystal & Co.*, 449 F.3d 377, 382 (2d Cir. 2006). The party opposing summary judgment, however, "may not rest upon the mere allegations or denials of the adverse party's pleading, but . . . must set forth specific facts showing that there is a genuine issue for trial." Fed. R. Civ. P. 56(e); *see also GlobalNet*, 449 F.3d at 382. The non-moving party may not rely upon speculation, but must "offer[] some hard evidence showing that its version of the events is not wholly fanciful." *Miner v. Clinton County*, 541 F.3d 464, 471 (2d Cir. 2008) (internal citations omitted).

II. Plaintiffs Prevail on the Merits of Their Claim that the FDA's "Plan of Action" Upon Remand and Execution Thereof Were Arbitrary and Capricious.

A. Standards for Review Under the APA

Under the APA, a district court may set aside an agency's findings, conclusions of law or action if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); *Tummino*, 603 F. Supp. 2d at 541-42. When inquiring as to whether an agency decision was arbitrary or capricious, the reviewing court "must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Marsh v. Or. Natural Res. Council*, 490 U.S. 360, 378 (1989) (internal quotation and citation omitted). Another important test is whether the agency has adhered to its normal practice. "The dominant law clearly is that an agency must either follow its own precedents or explain why it departs from them." 2 Richard J. Pierce, Jr., *Administrative Law Treatise* §11.5 (4th ed. 2002). As the United States Supreme Court has held, an agency has

a "duty to explain its departure from prior norms," *Atchison, Topeka, & Santa Fe Ry. Co. v. Wichita Bd. of Trade*, 412 U.S. 800, 808 (1973) (plurality opinion), and an irrational departure from a general policy by which its exercise of discretion will be governed could constitute arbitrary and capricious action in violation of the APA, *INS v. Yang*, 519 U.S. 26, 32 (1996). Accordingly, while the scientific review or risk benefit assessment of all proposed OTC drugs need not be evaluated in the same manner, an adequate explanation must be provided when a review "differ[s] in so many significant ways" from the review of other products. *Tummino*, 603 F. Supp. 2d at 548; *see also Burlington N.& Santa Fe Ry. Co. v. Surface Transp. Bd.*, 403 F.3d 771, 777 (D.C. Cir. 2005) ("Where an agency applies different standards to similarly situated entities and fails to support this disparate treatment with a reasoned explanation and substantial evidence in the record, its action is arbitrary and capricious and cannot be upheld."); *Bracco Diagnostics v. Shalala*, 963 F. Supp. 20, 28 (D.D.C. 1997) ("[t]he disparate treatment of functionally indistinguishable products is the essence of the meaning of arbitrary and capricious"). This is particularly so when there is evidence of actions taken in bad faith and in response to political pressure. *Tummino*, 603 F. Supp. 2d at 548.

Furthermore, when the FDA considers a factor or factors that it has not previously considered when determining an application, and that are not articulated in its own review regulations, its actions may be found to be arbitrary and capricious. In *Rhodia, Inc. v. FDA*, 608 F.2d 1376 (D.C. Cir. 1979), the court decided an appeal from an FDA denial of the plaintiff's supplemental new animal drug application (NADA). The court found that the FDA improperly considered whether changes in the supplemental NADA would increase available quantities of a new animal drug on the market as a factor in determining drug safety because there was no indication that the FDA had previously considered that factor, and the FDA's own regulations

"affirmatively exclude from the approval requirement . . . changes that appear to possess a potential for increasing quantities on the market." *Id.* at 1379. The court vacated the FDA order denying the supplemental NADA, stating:

> Once [the FDA] channels its discretion in a certain manner . . . the agency should follow that course consistently or articulate reasons for departure. In view of its previous course, bypassing quantity as a determinative criterion, the FDA may not now latch onto this factor as the basis for rejecting an otherwise-unobjectionable supplemental NADA.

Id.

As this Court explained, an agency decision also may be adjudged arbitrary and capricious:

> if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise. Moreover, proof of subjective bad faith by agency decision-makers, depriving a petitioner of fair and honest consideration of its proposal, generally constitutes arbitrary and capricious action.

Tummino, 603 F. Supp. 2d at 542 (internal quotations and citations omitted).

On an initial review of agency action, courts show some deference, but not "merely to rubber stamp" such actions. *Id.* ("To play that role would be tantamount to abdicating the judiciary's responsibility under the Administrative Procedure Act. On the contrary, to be upheld upon judicial review, the agency must have articulated a rational connection between the facts found and the choice made.") (internal quotations and citations omitted). But when reviewing agency action after remand, courts will accord an even "greater degree of scrutiny to an order that arrives at substantially the same conclusion as an order previously remanded by the same court." *Greyhound Corp. v. Interstate Commerce Comm'n*, 668 F.2d 1354, 1358 (D.C. Cir. 1981) (setting aside agency action when decision was same as one that triggered remand and granting plaintiff substantive relief sought from agency); *see also Guillen-Garcia v. INS*, 60 F.3d

340, 344 (7th Cir. 1995) ("[W]hen a case returns to us for a second time after we have remanded it with explicit instructions to the [agency], we examine with care the order of the [agency] to ensure that our earlier decision has been followed."); *Medicines Co. v. Kappos*, 731 F. Supp. 2d 470, 477 (E.D. Va. 2010) (same).

Here, as discussed in more detail below, the appropriate close review of the Secretary's and FDA's actions following remand demonstrates that they were arbitrary and capricious. The FDA first refused to reconsider the Citizen Petition at all, arguing that it could comply with the Court's Order by waiting indefinitely for and ruling on a drug application for a related EC product (Plan B One-Step), but at the same time refusing to apply that data to the Citizen Petition. This was nothing short of intentional avoidance of the Court's Order that the FDA go back and examine the complete files for the Citizen Petition and Plan B drug applications and conduct a fair and scientifically-based review of the Citizen Petition's request for unrestricted OTC status for Plan B and its generic equivalents. Indeed, even a fair review of the Plan B One-Step application would not have fully satisfied the Court's Order. Accordingly, this plan of action was made in bad faith, depriving Plaintiffs of a fair and honest consideration of the Citizen Petition. *See Tummino*, 603 F. Supp. 2d at 542.

Once the FDA chose that plan of action as a way to attempt to satisfy the Court's Order, it was further required to proceed in good faith and execute the plan in accordance with agency norms. However, as also discussed below, it did not do so, but instead executed the plan of action in an arbitrary and capricious manner. The review of the Plan B One-Step SNDA and the reasoning for the denial of the Citizen Petition departed in significant ways from assessments of other proposed OTC drug switch proposals without any adequate explanation. *See id.* at 548. Indeed, not only did the FDA disregard all of this Court's previous findings, but it again engaged

in precisely the type of bad faith and unprecedented actions that prompted a remand to the agency in the first place.

1. The FDA's Plan of Action for Complying with This Court's Order—To Wait for and Review a Potential SNDA for a Product It Asserts Is Not Covered by the Citizen Petition—Was Arbitrary and Capricious.

Each of the reasons below demonstrates that the FDA's supposed plan for complying with this Court's Order was arbitrary and capricious.

a. The FDA's refusal to review the extensive Citizen Petition/Plan B files was a deprivation of a fair and honest review of the unrestricted OTC switch request.

On remand, the FDA deviated from its normal practice without sufficient explanation and acted in bad faith by refusing to review the evidence in its possession relevant to Plan B. In remanding to the FDA to reconsider its decision on the Citizen Petition, this Court expressed trust that the newly appointed FDA leadership would "conduct a fair assessment of the scientific evidence." *Id.* at 549. As this Court noted, for years the relevant files have contained evidence sufficient to enable a full scientific review of the Citizen Petition. *Id.* at 526, 543. The FDA even admitted that a fair reconsideration of the denial of the Citizen Petition would require it to first determine from the relevant files if sufficient data exist to support an OTC switch for all age groups. Def.'s Mem. in Opp'n to Contempt 9-10, 22, 26, 31. But the FDA chose to do no assessment whatsoever of this data in its possession. Instead, it chose to wait indefinitely for an SNDA for a different product to be filed with adolescent-specific data that it later admitted it would not apply to the Citizen Petition, *see supra* Facts § F(2).[5] Such actions defy common sense, are a departure from agency norms, and are "proof of subjective bad faith . . . depriving a

[5] Indeed, by insisting that the drug sponsor gather and submit such data, the FDA unnecessarily created additional bases on which both the Plan B One-Step SNDA and the Citizen Petition could be denied. And as Plaintiffs eerily predicted, both were ultimately denied because of specious concerns about the inadequacy of the demanded data. *See* Pls.' Ltr. to the Court 3 (May 31, 2011) (ECF No. 329).

petitioner of fair and honest consideration of its proposal." *Tummino*, 603 F. Supp. 2d at 542; Pendergast Decl. ¶ 9, 21, 24. Thus, the FDA's actions were arbitrary and capricious. *Tummino*, 603 F. Supp. 2d at 542.

This refusal to consider the relevant evidence in its possession was particularly egregious here, where the FDA had every reason to believe that a fair and scientific assessment of the Citizen Petition/Plan B files would have led it to grant the Citizen Petition without restriction. Indeed, even as far back as 2001, the FDA noted that the Citizen Petition met the criteria for unrestricted OTC availability and was supported by scientific data. *Tummino*, 603 F. Supp. 2d at 526; *see also id.* at 526-35, 538 (describing unrebutted evidence that data on Plan B was sufficient to approve OTC availability for all ages); *accord* Pendergast Decl. ¶ 9 (explaining FDA's 1997 "understanding that post-coital contraception would have been appropriate for OTC use from the very beginning"). The label comprehension and actual use studies provided more than enough data to support the conclusion that all women, regardless of age, could understand the Plan B label and use the product safely and effectively without consultation with a licensed practitioner. Raymond Decl. ¶¶ 6, 21, 23, 27-28; Pendergast Decl. ¶ 12-15, 17; Pls.' Mem. in Supp. of Summ. J. Ex A-2 T-30757 (ECF No. 235-2) (Dr. Rosebraugh commenting that "[i]f this is not enough data upon which to base a decision, it is unclear what would constitute enough data or even if that is an obtainable goal"). The FDA was on notice from this Court's Order that its prior refusal to extrapolate data from adults to adolescents was a departure from its normal procedures, based on political considerations, that led to a finding of bad faith. *See Tummino*, 603 F. Supp. 2d at 546, 547-49. Yet that is exactly what the FDA did a second time by insisting on and awaiting new teen-specific data instead of reconsidering the Citizen Petition.

b. The FDA's chosen course of action on its face reveals a preordained determination that the FDA would not grant the Citizen Petition.

The FDA's plan to comply with this Court's Order by waiting for the filing of the Plan B One-Step SNDA along with the adolescent-specific data that the agency had forced the drug sponsor to gather and submit was not a path for a fair, honest and scientific review of the Citizen Petition. Rather, it was a path only to deny the petition or avoid ruling on it. As the FDA admitted in its eleventh-hour denial of the Citizen Petition, "if additional data regarding the OTC use by younger women were needed for Plan B One-Step, that type of data would also be needed for Plan B, but those Plan B One-Step studies would not be transferable to Plan B." Cit. Pet. Denial Ltr. Dec. 12, 2011 at 2. Years before the Plan B One-Step SNDA was submitted, however — in continued support of its earlier politically-motivated decision — the FDA had already concluded that additional data were necessary and communicated that conclusion to the Plan B One-Step sponsor. Accordingly, by its own reasoning, once it drew that conclusion about Plan B One-Step years earlier, it automatically determined that the existing data supporting the Citizen Petition was deficient.[6]

Indeed, it would have been illogical for the FDA to devise a plan to wait for the Plan B One-Step application and adolescent-specific data before ruling on the Citizen Petition unless it had also already determined that it would eventually deem such data necessary for a Citizen Petition grant. If the FDA was open minded in its reconsideration of the Citizen Petition, why would it wait years to review additional data – which it might conclude was unnecessary after

[6] That the FDA had already concluded that it would not grant the Citizen Petition unless more data was filed is also apparent from numerous court filings. *See, e.g.*, Def.'s Mem. in Opp'n to Contempt 31 (ECF No. 315) (complaining that Plaintiffs "have not submitted additional evidence or information in support of the Citizen Petition"); *see also id.* at 8; Def.'s Reply to Pls.' Responses to Court Order 4 (ECF No. 333) (expressing doubt that Citizen Petition would be granted without new evidence); Def.'s Mem. in Opp'n to Contempt 6 (stating that two-pill generics could seek all ages OTC status "were they to obtain appropriate data").

all, leading it to go back to review the existing Citizen Petition files? It is clear that before the Plan B One-Step SNDA was even filed, the FDA had already determined that eventually it would: (1) deem the Plan B One-Step adolescent-specific data to be necessary; and (2) use that determination to conclude that the data supporting the Citizen Petition was insufficient.[7]

This Court originally determined that the FDA's decision to reject a Plan B SNDA before the scientific reviews had even been completed was a basis for concluding that the "consideration" had been conducted in bad faith and was arbitrary and capricious. *Tummino*, 603 F. Supp. 2d at 547. The same conclusion must be reached here. The FDA's predetermination of the fate of the Citizen Petition on remand, before looking at the Citizen Petition/Plan B files was arbitrary and capricious for "depriving . . . petitioner of fair and honest consideration of its proposal." *Id.* at 530, 542; Jenkins Dep. 33:12-17; *see also id* at 29:7-19.

c. Even if approval of the Plan B One-Step SNDA had been assured, such action would still deprive Plaintiffs of a fair and honest consideration of the Citizen Petition.

The FDA has taken the position that the relief requested by the Citizen Petition does not extend to Plan B One-Step, *see* Def.'s Reply to Pls.' Responses to Court 1-2. But if that is correct, the FDA's consideration of the *Plan B One-Step* SNDA could not possibly have satisfied the agency's obligation to rule on the Citizen Petition regarding *Plan B*. *Tummino*, 603 F. Supp. 2d at 550 (ordering the FDA to "reconsider its decisions regarding the *Plan B* switch to OTC use") (emphasis added). The FDA apparently takes the position that as long as it took any action with respect to any EC product, it need not comply with the Court's Order. But the FDA does

[7] Indeed, although the FDA may have thought it was being clever, Plaintiffs completely foresaw the convoluted path the agency had mapped out to try to avoid reconsideration of the Citizen Petition. *See* Pls.' Ltr. Response to Court Order 2 (ECF No. 329) ("[G]iven the FDA's insistence on receiving age-specific data despite its long-standing practice of extrapolating from data on adults, an approval of the [Plan B One-Step] SNDA alone would most likely correspond with an agency determination that the age-specific data was 'essential' to the SNDA approval, thereby *preventing* removal of the restrictions on other brands for three years.") (citing 21 U.S.C. 355(c)(3)(E)(iii)).

not get to refashion Court orders on its own. A plan for compliance that ignores the Court's order is an act of bad faith, depriving Plaintiffs of fair and honest consideration of its petition, and is therefore arbitrary and capricious. *Id.* at 542.

The egregiousness of the FDA's plan is apparent when one considers the practical result of it. As the FDA has acknowledged, ruling on the Citizen Petition would have paved the way for full OTC status not only of Plan B, but of two levonorgestrel-based emergency contraception generic products currently marketed, as well as any new generics. Novak Decl., Ex. D; Def.'s Reply to Pls.' Responses to Court Order 2-3.[8] In contrast, approval of the Plan B One-Step SNDA would permit full OTC status only for Plan B One-Step, and prohibit other EC products from being available OTC for three years. Cit. Pet. Denial Ltr. Dec. 12, 2011 at 6, 9; Pendergast Decl. ¶ 22. Accordingly, a grant of the Citizen Petition would secure broad access to emergency contraception,[9] while an approval of the Plan B One-Step SNDA would not. Although Plaintiffs have, for the past ten years, stressed the importance of OTC access to generic versions of EC—including in letters to the FDA after remand, Letter from Suzanne Novak (May 19, 2009) (ECF No. 307-3 at 2-3); Letter from Suzanne Novak (Aug. 17, 2009) (ECF No. 307-3 at 9-10). the FDA believes it is their prerogative to decide that Plaintiffs should have been satisfied with (the prospect of) just one name-brand being made available OTC. Def.'s Reply to Pls.' Responses to Court Order 3. Supposedly complying with the Court's Order to reconsider the Citizen Petition

[8] Contrary to the FDA's repealed contentions, rulemaking would not be required to effectuate an OTC switch, even in the absence of an SNDA. Pendergast Decl. ¶¶ 26-28. The FDA can take the initiative to switch a drug to OTC status any time it determines that there is sufficient evidence that an OTC switch will not harm the public health. *Id* .¶ 26. The FDA has proven its ability to act without rulemaking in the past by publishing a notice in the Federal Register requesting new drug applications for certain forms of emergency contraception, *id.*¶¶ 6-7, and by changing the age cutoff for Plan B from 18 to 17, *see* Def.'s Mem. in Opp'n to Contempt 6; Declaration of Jane A. Axelrad (hereinafter "Axelrad Decl.") ¶¶ 3-5, Exs. A-C.

[9] After granting the Citizen Petition, the FDA could then implement the decision by inviting all relevant drug manufacturers to submit supplemental applications and proposed labeling, and then quickly approve them, as it did with respect to approval of marketing emergency contraception to 17 year olds following this Court's 2009 order. *See* Def.'s Mem. in Opp'n to Contempt 6; Axelrad Decl. ¶¶ 3-5, Exs. A, B, C.

by devising a plan that could not possibly have resulted in the relief sought in the petition is an act of bad faith.

B. The FDA's Actions on Remand Were Arbitrary and Capricious.

Both actions the FDA took on remand related to the Citizen Petition were arbitrary and capricious. First, it acted arbitrarily and capriciously in its consideration of the Plan B One-Step SNDA—the agency's proposed means of complying with the Court's Order. In addition, its second denial of the Citizen Petition was arbitrary and capricious.

1. Denial of the Plan B One-Step Application Was Arbitrary and Capricious

The FDA's plan for complying with this Court's Order was to consider the SNDA to make Plan B One-Step available OTC with no restrictions. Once the FDA devised its plan for compliance it was required to execute that plan in good faith and not in an arbitrary and capricious manner. But the FDA hopelessly failed in that regard – due to the Secretary's order directing FDA staff to deny the SNDA for Plan B One-Step. Indeed, it is striking how the actions and reasoning leading to the ultimate denial of the Plan B One-Step SNDA mirror the actions and reasoning that led to the denials of the earlier switch applications for Plan B that prompted this Court's arbitrary and capricious findings. It seems almost surreal that the FDA's actions and reasoning were even more egregious this time around.

As discussed earlier, *see supra* Facts § E**,** this Court concluded that the FDA had acted arbitrarily and capriciously with respect to the Citizen Petition and Plan B based on the following nine findings: (1) the FDA's course of conduct regarding Plan B departed in significant ways from the agency's normal procedures for requested OTC switches, notably:

(2) FDA upper management, including the Commissioner, wresting control over the decision-making process from staff that normally would issue the final decision

(3) Denying full OTC access without age restriction against the recommendation of the scientific review staff;
(4) Discussions with the White House about an OTC switch;
(5) The FDA making a decision to reject the first SNDA before the scientific reviews had been completed; and,
(6) Insistence on additional data for adolescents when data on adolescents already existed and there was a long agency history of extrapolating data to adolescents, particularly with respect to contraception

In addition, (7) the FDA took political considerations into account when considering and ruling on Plan B; (8) the FDA had implausible justifications for its decision-making on Plan B; and (9) the FDA repeatedly and unreasonably delayed issuing a decision on Plan B. *See supra* Facts § E; *Tummino*, 603 F. Supp. 2d at 544-48**.** Except for the fifth finding and the ninth finding of unreasonable delay (which does apply to the FDA's actions regarding the Citizen Petition discussed below), *all other findings apply to the FDA's treatment of the Plan B One-Step application.*

a. Same departures from normal agency procedures

The FDA's treatment of the Plan B One-Step SNDA departed significantly from actions taken on other OTC switch applications. As with respect to Plan B, "FDA upper management, including the Commissioner, wrested control over the decision-making process from staff that normally would issue the final decision." *Tummino*, 603 F. Supp. 2d at 523. As this Court previously noted, the Commissioner of Food and Drugs delegated authority over OTC switch applications to CDER. *Id.* at 525. Such applications are reviewed by two offices within CDER, and the directors of those two offices. If the Director of CDER disagrees with the office-level decision, he or she may change it. *Id.* As this Court found, it was a significant departure from usual FDA procedures for the FDA to require the Plan B switch application to be approved or signed off by someone as high up at the FDA as the Commissioner. *Id.* at 530, 534, 537. On the Plan B One-Step switch application, the final decision was made at *an even higher level*—by the

Secretary of Human and Health Services. Press Release, Statement by U.S. Department of Health and Human Services Secretary Kathleen Sebelius (Dec. 7, 2011) (ECF No. 339-1 at 4). This was not only "unusual," but unprecedented. It is believed that it is the first time in history that the HHS Secretary has overruled a product approval decision by the FDA. Pendergast Decl. ¶¶ 33-34.

The second departure from FDA norms that took place regarding Plan B was denying full OTC access without age restriction against the recommendation of the scientific review staff. The same action occurred with respect to Plan B One-Step. The Commissioner of Food and Drugs, Dr. Hamburg, stated that "CDER experts, including obstetrician/gynecologists and pediatricians, reviewed the totality of the data and agreed that it met the regulatory standard for a nonprescription drug and that Plan B One-Step should be approved for all females of child-bearing potential." FDA, Statement from FDA Commissioner Margaret Hamburg, M.D. on Plan B One-Step (December 7, 2011) (ECF No. 339-2). She further stated that she reviewed and thoughtfully considered the data, clinical information, and CDER analysis and agreed that there "is adequate and reasonable, well-supported, and science-based evidence that Plan B One-Step is safe and effective" and should be approved OTC without age restrictions. *Id.* But HHS Secretary Sebelius—who is not a doctor, has no scientific training and does not claim to have reviewed anything other than the FDA's Division Director Summary Review of Regulatory Action for the Plan B One-Step SNDA—overruled the recommendation of the scientific staff, purportedly on grounds regarding the sufficiency of the data and other scientific considerations. *See* Press Release, Statement by U.S. Department of Health and Human Services Secretary Kathleen Sebelius (December 7, 2011) (ECF No. 339-1 at 4).

The third significant departure from FDA norms that occurred around the efforts to make Plan B accessible OTC was discussions with the White House about the OTC switch. As this Court recognized, "[w]hether or not it was permissible for the FDA to discuss such questions with the White House, these discussions were not the norm for the FDA with respect to this type of decision." *Tummino*, 603 F. Supp. 2d at 547. Such communications, however, again took place with respect to the Plan B One-Step application. Press Secretary for the White House, Jay Carney, admitted that there were communications between the White House Staff and Secretary Sebelius or her staff about the potential OTC switch for Plan B One-Step. Press Release by Jay Carney, The White House, Office of the Press Secretary (Dec. 8, 2011), http://www.whitehouse.gov/the-press-office/2011/12/08/press-briefing-press-secretary-jay-carney-1282011 (last visited Feb. 7, 2012).

The next point of departure from FDA norms that occurred with respect to Plan B was the FDA's insistence on new data for adolescents when data on adolescents already existed, the FDA had assured the drug sponsors that the data being gathered was sufficient, and there was a long agency history of extrapolating data to adolescents, particularly with respect to contraception. *See id.* at 526-27; 532-33**,** 547-48. For Plan B, CDER Acting Director Dr. Galson expressed concern about the small number of data regarding "younger adolescent[s]," particularly in the actual use study: he refused to extrapolate the findings from the actual use study from older to younger teens, expressing concern over the developmental differences between early and mid-adolescence. *Id.* at 532-33. This Court and a Congressional inquiry concluded that these actions and justifications were novel departures from normal agency procedures. *Id.* at 537-38, 544-49.

The same departures occurred with respect to Plan B One-Step, but even more egregiously. The Plan B One-Step's drug sponsor bowed to the FDA's demands that it initiate a

study solely of teens, *see* Harper Decl. ¶ 8, worked closely with the FDA in devising the studies, *see* Raymond Decl. ¶¶ 31, 33; Harper Decl. ¶¶ 10-13, 15, 17, and conducted studies in which 680 adolescents participated, Harper Decl. ¶¶ 18-19 (345 participants); Raymond ¶ 34 (335 participants). Even with that large number of adolescents, Secretary Sebelius refused to allow the FDA scientists to extrapolate within the teen group, expressing the identical concerns that Dr. Galson had about cognitive development. Secretary Sebelius highlighted the hypothetical 11 year old for whom menstruation has begun and who *could, theoretically*, purchase and use EC.

b. Political considerations

Another basis upon which this Court determined that the FDA had acted arbitrarily and capriciously in consideration of Plan B was that the FDA took political considerations into account when considering and ruling on the proposed switch. Common sense and the evidence in this case demonstrate that such unusual involvement by the White House in a drug OTC switch application such as Plan B One-Step is indicative of political considerations infiltrating the switch application process. And, as this Court has noted, "the mere existence of 'extraneous pressure' from the White House or other political quarters . . . [in and of itself] render[s] [an OTC switch] decision invalid." *Tummino*, 603 F. Supp. 2d at 545.

c. Implausible justifications

The final applicable basis for the Court's holding that the FDA had engaged in bad faith and arbitrary and capricious behavior with respect to Plan B was the FDA's implausible justifications for its decision-making on Plan B. This Court found "[t]he hypothetical enforcement issue [to be] an implausible explanation for the decision to deprive 17 year olds, whom the FDA has concluded can use Plan B OTC safely, of the much enhanced ease of obtaining Plan B without a prescription." *Tummino*, 603 F. Supp. 2d at 550. Equally implausible

is Secretary Sebelius's focus on the hypothetical 11 year old supposedly using emergency contraception and the scientific insufficiency of the data regarding that 11 year old. This justification is implausible for numerous reasons. First, the Secretary's justification is nonsensical—the reason there is little to no data regarding 11 year olds is because, as the actual use studies confirmed, 11 year olds do not use the product. Harper Decl. ¶¶ 13-18. Second, even if the studies did include the rare 11 year old who seeks EC, the information gathered would not be particularly useful because no conclusions could be drawn about 11 year olds as a group given the incredibly small number of 11 year old EC users. Harper Decl. ¶ 14; *see also* Raymond Decl. ¶ 37. Indeed, the implausibility of this justification is demonstrated by the Secretary's subtle sleight of hand when explaining her reasoning:

> the switch from prescription to over the counter for this product requires that we have enough evidence to show that those who *use* this medicine can understand the label and use the product appropriately. I do not believe that Teva's application met that standard. The label comprehension and actual use studies did not contain data for all ages for which this product would be *available for use*.

Press Release, Statement by U.S. Department of Health and Human Services Secretary Kathleen Sebelius (December 7, 2011) (emphasis added) (ECF No. 339-1 at 4). This rationale mixes apples and oranges. Actual use studies are precisely that—studies to simulate the use of a product by persons who would *actually use* a product. Harper Decl. ¶ 5. There were no 11 or 12 year olds in that study because a miniscule number of persons those ages use EC. *Id.* ¶¶ 13-18. It is true, however, that if granted OTC status, Plan B One-Step, *like OTC products generally*, would be "available" to persons of all ages, including 11 year olds and 91 year olds, because it would be placed on the shelf of a store, available for purchase. But under Secretary Sebelius' reasoning, no product could ever become available OTC unless every potential consumer, no matter how young and no matter how small the likelihood that they would consume the product,

were included in actual use studies, thus eviscerating the whole purpose and meaning of an actual use study.

Third, Secretary Sebelius' concern about 11 year olds is implausible as a justification for ordering the Plan B One-Step SNDA to be denied because when the agency in the past has lacked confidence in the applicability of manufacturers' studies in OTC switches to younger consumers, it has required a label warning, rather than an age restriction or outright denial. Pls.' Mem. in Supp. of Summ. J. 71 (citing Jenkins Dep. 91:11-19, 113:7-16, 118:13-119:9).[10] OTC status is default status for drugs. A drug should be limited to prescription status only when "because of its toxicity or other potentiality for harmful effects [or other harms], [it] is not safe for use except under the supervision of a practitioner licensed by law to administer [it]." 21 U.S.C. § 353(b)(1)(A). Unlike many other OTC drugs, EC does not have serious side effects. *Tummino*, 603 F. Supp. 2d at 522; Raymond Decl. ¶ 8. Finally, Secretary Sebelius lacks any training or expertise to make judgments about the sufficiency of data, particularly as justification for taking the unprecedented act of overruling the Commissioner of Food and Drugs on a scientific determination.

Indeed, this is a classic example of continuing to move the goalposts so that the desired goal can never be attained. The FDA forced the Plan B One-Step sponsor to do additional, unprecedented and unnecessary studies just of adolescents, rather than adhering to longstanding agency practice of extrapolating data for adolescents. It gave input and guided the methodology of the underlying studies. It wanted actual use studies, which, by definition, study only those that use the product. But then it denied the Plan B One-Step SNDA because the studies did not

[10] Indeed, not only would failure to follow directions by taking the two pills at the same time not cause any adverse effects, but "[s]tudies have shown that Plan B is equally effective if the two doses of levonorgestrel are taken less than 12 hours apart or at the same time." *Tummino*, 603 F. Supp. 2d at 522.

have data for persons who, though the product was available to them, *did not request its use over the course of two years*.

* * *

In its Order, this Court found that "[t]he FDA simply has not come forward with an adequate explanation" as to "why the review of Plan B differed in so many significant ways from the review of other switch applications," *Tummino*, 603 F. Supp. 2d at 548, prompting a finding of bad faith and arbitrary and capricious decisionmaking, *id.* at 542, 544. The same holds true for Plan B One-Step. It has been repeatedly shown that emergency contraception is safe and effective for self-administration and that its labeling clearly provides directions for safe use and warnings regarding unsafe use, side effects, and adverse reactions. *See* 21 C.F.R. § 310.200(b); § 330.10(a)(4); *Tummino*, 603 F. Supp. 2d at 525. There is no justification for why the review of the Plan B One-Step SNDA differed in so many significant ways from the review of other switch applications (except, of course, the review of Plan B, which it mirrored). Against the backdrop of 10 years of bad faith tactics and implausible reasoning for denying OTC status to emergency contraception, there is only one explanation for why the FDA engaged in virtually the same—but even more egregious—arbitrary and capricious actions than it did for Plan B: political considerations will never permit science to prevail for EC. Such continued bad faith actions constitute invalid arbitrary and capricious actions. *See Tummino*, 603 F. Supp. 2d. at 542.

2. The December 12, 2011 Denial of the Citizen Petition Was Arbitrary and Capricious.

The FDA's second denial of the Citizen Petition was arbitrary and capricious. This Court vacated the original denial of the Petition because the FDA had failed to conduct a fair and scientifically based review of the relevant files. Yet, the FDA specifically *relied* on the vacated denial and the reasons underlying it in issuing the second denial and again failed to assess the

Citizen Petition/Plan B files objectively and in accordance with agency procedures. Because the FDA arrived at the same conclusion as the one previously vacated, a great degree of scrutiny towards the second denial is warranted. *See supra* Part II(A); Pendergast Decl. ¶ 18. As described earlier, the FDA put forth four reasons for denying the Citizen Petition for a second time: (1) Dr. Galson's determinations in 2005 that the Citizen Petition/Plan B files could not support an OTC switch because of insufficient data on adolescents; (2) the lack of actual use and label comprehension studies submitted with the Citizen Petition; (3) Plaintiffs' failure to submit additional data after the FDA re-opened the docket for the Citizen Petition following this Court's Order; and, (4) the data submitted with the Plan B One-Step application was necessary—and therefore such data would be necessary for the Citizen Petition—but the Plan B One-Step data could not be applied to Plan B because of the latter's "more complicated directions for use" (2 pills instead of one). *See supra* Facts § H at 17-18.

But these bases show complete disregard of this Court's findings and Order. The first three reasons were the same reasons the FDA cited for its original denial that this Court held to be arbitrary and capricious, prompting it to vacate the denial in the first place. And the fourth is drawn from neither the data and studies regarding Plan B nor from what the FDA recounted, in the denial letter itself, as the important aspects of the studies submitted in support of the Plan B One-Step SNDA. Indeed, the FDA failed to do what it had previously admitted would be a first step for a fair and honest reconsideration of the Citizen Petition—determining from the existing relevant files if sufficient data exists to support an OTC switch for all age groups. Def.'s Mem. in Opp'n to Contempt 9-10, 22, 26, 31.

The FDA first attempts to justify its reliance on Dr. Galson's conclusions that there was insufficient data on adolescents by stating that "the court did not reject . . . FDA's determination

that neither the Citizen Petition nor the Plan B SNDA contained [adequate data demonstrating that the statutory standards were satisfied] for women under the age of 17." Cit. Pet. Denial Ltr. Dec. 12, 2011 at 5. But the Court *did* reject that determination. It held that the Plaintiffs' unrebutted evidence demonstrated that the FDA's *entire* decision making process regarding both the Citizen Petition and the SNDAs—and therefore any "determinations" made therefrom—was conducted in bad faith and in response to political pressure. *Tummino*, 603 F. Supp. 2d at 544-49. More importantly, the Court specifically identified Dr. Galson's motivations and conclusions as examples of the FDA's bad faith and arbitrary and capricious actions that required the denial of the Citizen Petition to be vacated. The Court noted that Commissioner von Eschenbach's "concern about the inadequacy of data available for young adolescents" was motivated by political pressure from the White House, and that "the Commissioner transmitted this pressure down the chain of command at the FDA: pressuring Dr. Galson not to approve over-the-counter use of Plan B without age restriction." *Tummino*, 603 F. Supp. 2d at 546; *see also id.* at 529 (discussing evidence that Dr. Galson thought he would lose his position at the FDA if he did not succumb to pressure from the White House); *id.* at 530 (stating that, at the time Dr. Galson told FDA staff that the FDA would deny first SNDA, he was unaware of additional data on use by adolescents); *id.* at 533 (stating that Dr. Galson's concerns were contradicted by data). And the Court held that one of the departures from normal procedures that showed the FDA's lack of good faith was the agency's—and particularly Dr. Galson's—refusal to extrapolate actual use study data from older to younger adolescents. *Id.* at 538; *see also id.* at 547-48.

The next two reasons the FDA put forth to deny the Citizen Petition for the second time were the lack of label comprehension and actual use studies submitted with the Citizen Petition

originally, and Plaintiffs' failure to submit such studies after the Petition file was reopened on remand. But these two reasons are unjustifiable and set forth in bad faith. This Court already ruled that the issues presented by the Plan B SNDAs and the Citizen Petition were one and the same, *id.* at 537, and therefore their files were relevant to each other. Second, despite the FDA's continuous repeating of its reasoning for originally denying the Citizen Petition—that additional evidence concerning adolescents was necessary—this Court determined that such reasoning was unfounded and infiltrated by political considerations. Accordingly, it was arbitrary and capricious for the FDA to deny the petition based on a failure to submit more data.

The FDA's final reason for denying the Citizen Petition—the one that it has been working for years to set in place—is that the data from the studies submitted with the Plan B One-Step SNDA do not support the Citizen Petition because they do not show that "women under 17 can understand that they would need to take two pills twelve hours apart, and whether they would actually do so correctly," Cit. Pet. Denial Ltr. Dec. 12, 2011 at10, but that such studies are "necessary" for OTC approval for Plan B. Cit. Pet. Denial Letr. Dec 12, 2011 at 10. Against the backdrop of a decade of the FDA's bad faith and arbitrary and capricious decision making regarding EC—including such recycled bad faith reasoning on remand—this final excuse for re-denying the Citizen Petition is simply implausible. First, it ignores that for at least eight years the FDA *has had* data in its possession showing that women of all ages "understand that they would need to take two pills twelve hours apart, and [that] they would actually do so correctly." *Id.* Second, this reasoning ignores this Court's holding that it was arbitrary and capricious not to extrapolate the relevant Plan B data from older to younger women as the FDA does for all other drugs (especially contraceptives), or sufficiently explain why EC warrants different treatment. The FDA doesn't explain why the adolescent-specific data submitted with

the Plan B One-Step SNDA is "necessary" beyond just saying it is, when the crux of this Court's Order was that the FDA has never deemed such data as "necessary" before.

Third, the FDA fails to adequately explain (or explain at all) why the instructions for Plan B are "so complicated" that, given the existing actual use and label comprehension data in the Citizen Petition/Plan B files, plus the additional actual use and label comprehension data in the Plan B One-Step file that confirmed the earlier findings, new studies would need to be performed for Plan B to demonstrate that it meets the standard for full (and ordinary) OTC status.[11] Moreover, all of the FDA-determined "key" findings from the Plan B One-Step studies apply equally to both one-pill and two-pill EC products and do *not* relate to the number of pills or difference in directions. *Id.* at 8-10; Raymond ¶ 36. And, because the dosing of a particular EC product is applicable to all women who take it, EC is much *simpler* than many medications currently sold OTC that require tailoring of a dose based on patient characteristics (such as age) or therapeutic response. Raymond ¶ 10. Consumers regularly follow much more complicated instructions for other OTC products than taking one pill as soon as possible and the second, identical dose, 12 hours later. *Id.* Moreover, failure to understand and abide by the 12-hour dosing interval for the two-pill EC is irrelevant to both efficacy and safety. *Id.* ¶ 36. Indeed, that the FDA deems a difference in dosage from one pill to two so "complicated" as to necessitate additional studies is simply not credible. Pendergast Decl. ¶ 20-21. There are hundreds of drugs available OTC that come in a variety of compositions (gels, tablets, liquid) with different instructions about when and how many to take.

[11] Furthermore, the FDA has never explained how the prescription requirement would solve any supposed label comprehension issues with the two-pill products. A teenager who obtains a prescription from a physician for EC would still be required to follow the instructions on her own, counting out the twelve hours between pills. Pendergast Decl. ¶ 26.

The FDA itself acknowledges that actual use and label comprehension studies are not always required, particularly if a drug has previously been approved for OTC use, like levonorgestrel-based EC has been—in two-pill form—since 2006. Cit. Pet. Denial Ltr. Dec. 12, 2011 at 4**;** *see also supra* Facts § D. And given that label comprehension studies are discretionary—and rarely contain data on adolescents, *see* Pls.' Mem. in Supp. of Summ. J. Ex. E (ECF No. 235-10 at 18-19) — it is inexplicable —from a scientific standpoint —why an additional study of that kind would be required here. Moreover, by requiring data ad infinitum in order for EC to be fully available OTC, the FDA turns the appropriate approach to prescription versus OTC availability on its head. OTC status is the default status for drugs and EC should be limited to availability by prescription *only if* it is not safe for OTC use because of its toxicity or other possible harmful effects, *see* 21 U.S.C. § 353(b)(1)(A), a description that the FDA neither can nor does contend applies to EC. *Cf.* Pendergast Decl. ¶¶ 23, 26.

The FDA's second denial of the Citizen Petition was arbitrary and capricious and made in bad faith for numerous reasons. It failed to give the Citizen Petition fair and honest consideration, *see Tummino*, 603 F. Supp. 2d at 542, by ignoring this Court's previous findings and again departing from normal agency procedures by insisting on additional teen-specific data in support of an OTC switch for Plan B. It also departed from agency procedures and failed to give the required fair review by denying the petition on the basis of determinations made regarding another product. But the FDA has not made any attempt to explain the rationale for such departures. *See id.* at 548. Finally, given the plethora of data supporting an OTC switch for Plan B for all women—the original studies confirmed by the Plan B One-Step studies— as well as the optional and discretionary nature of submitting studies in the first place, the FDA's denial

of the Citizen Petition for lack of additional, teen-specific data focusing on the two-pill nature of Plan B is simply implausible. *See id.* at 542.

III. Plaintiffs are Entitled to Both a Preliminary Injunction and Summary Judgment in their Favor.

A. Preliminary Injunction

As shown above, *supra* Part II, Plaintiffs have established a substantial likelihood of success on the merits of their claim that the FDA's actions on remand were arbitrary and capricious. In addition, Plaintiffs face irreparable harm if they are not afforded injunctive relief. As explained above, *supra* Facts § D, the BTC regime creates substantial obstacles to *all women's* access to EC. Women under 17 obviously face the barrier of having to find a physician and obtain a prescription. But all women face barriers to access: many women do not live near a pharmacy, or the pharmacies in their community may not be open 24 hours; many women do not have government-issued ID or do not want to reveal their identities to the seller. *See* Wilkinson Decl. ¶ 9. And because of the complexity and uniqueness of the BTC regime, it is often implemented incorrectly by pharmacists, such as those who tell 17 year olds that they cannot buy EC over the counter. *Id.* ¶ 8. All of these barriers can delay access to EC, which decreases the drug's effectiveness, and they may prevent some women from accessing EC altogether. *Id* ¶ 10. This places the individual plaintiffs and the women whose access to EC all the Plaintiffs seek to expand at risk of unintended pregnancy because of obstacles to accessing contraception, which implicates their fundamental rights. *See, e.g.*, *Carey v. Population Servs. Int'l*, 431 U.S. 678, 685 (1977) (explaining, in context of evaluating constitutionality of restrictions on purchase of contraception, that the right to privacy protects the decision whether to beget a child). This harm cannot be adequately compensated by a monetary award, and so it is irreparable. *See Wisdom*

Imp. Sales Co. v. Labatt Brewing Co., 339 F.3d 101, 113 (2d Cir. 2003) (internal citations omitted).

Furthermore, the public interest weighs in favor of immediate injunctive relief. The safety and efficacy of EC for self-administration has been well established by scientific evidence. *See, e.g.*, FDA, Statement from FDA Commissioner Margaret Hamburg, M.D. on Plan B One-Step (Dec. 7, 2011) (ECF No. 339-2). The broader access to EC that Plaintiffs seek would have a positive effect on public health, as well as facilitate the intent of the FDCA to "to relieve retail pharmacists and the public from burdensome and unnecessary restrictions on the dispensing of drugs that are safe for use without the supervision of a physician." *Tummino*, 603 F. Supp. 2d at 525 (internal citations omitted). Pendergast Decl. ¶ 26. Neither the FDA nor the public benefits from keeping in place barriers to women trying to access a safe method of birth control that must be taken as soon as possible to prevent an unwanted pregnancy.

B. Summary Judgment

Summary judgment in favor of the Plaintiffs is warranted. First, there are no disputed issues of material fact. (If the FDA contests any of the facts presented in support of Plaintiffs' underlying motion, Plaintiffs hereby move to reopen discovery immediately.) Second, Plaintiffs are entitled to judgment as a matter of law, as the evidence shows that the FDA's treatment of the Citizen Petition and Plan B One-Step SNDA on remand was arbitrary and capricious in violation of 5 U.S.C. § 706(2)(A).

Plaintiffs seek permanent injunctive relief. "Generally, to obtain a permanent injunction a party must show the absence of an adequate remedy at law and irreparable harm if the relief is not granted." *N.Y. State Nat'l Org. for Women v. Terry*, 886 F.2d 1339, 1362 (2d Cir. 1989). As

argued above regarding Plaintiffs' prayer for a preliminary injunction, this standard is satisfied here.

REQUEST FOR RELIEF

In its March 2009 Order, this Court explained that "when a court reviewing an agency decision rules in favor of the plaintiff, it generally remands to the agency rather than granting affirmative relief" noting that "[c]ertain circumstances, however, warrant exception to this general remand rule." *Tummino*, 603 F. Supp. 2d at 549. The Court explained that remand would serve no useful purpose and that a court should order the desired agency action when: (1) "a court has found that an agency decision is not supported by the record, but 'the record has been fully-developed;'" or (2) when a justification for agency action "runs counter to the evidence and is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.* at 549 (internal quotations and citations omitted). On those bases, the Court directed the FDA to permit the Plan B drug sponsor to make Plan B available to 17 year olds without a prescription, within thirty days. *Id.* at 550.

Such circumstances are present here. The record for both Plan B and its generic equivalents, as well as Plan B One-Step, is fully developed, but the final agency decision regarding both products is not supported by the record—the scientific review staff for both Plan B and Plan B One-Step found that the criteria for EC to be available OTC without age or other restriction had been met.

Moreover, the justifications for the denial of the Plan B One-Step OTC SNDA and the second denial of the Citizen Petition "run[] counter to the evidence and [are] so implausible that [they] could not be ascribed to a difference in view or the product of agency expertise." *Id.* at 549 (internal quotations omitted). Regarding the denial of the Plan B One-Step OTC SNDA, the

seeming concern about the very young adolescents (11 year olds) is simply implausible. As previously discussed, virtually no 11 year olds use this product, and the FDA handles concerns about much more dangerous products by putting warnings on the labels. Finally, there is nothing in the record indicating why Plan B One-Step warrants treatment that is so different than other OTC requests. Regarding the second denial of the Citizen Petition, as also previously discussed, the justifications rested upon determinations that this Court previously found to be infiltrated by politics. The rationale of needing more teen-specific data is further not credible because there was no explanation for why such data would be needed only for EC, particularly when the earlier data demonstrated that teens could safely and effectively use EC without consulting a practitioner and the Plan B One-Step data confirmed those findings.

Remand would serve no useful purpose here. The evidence and scientific consensus is overwhelming that EC is safe and effective for women of all ages to use without a prescription and without restriction. The evidence (along with common sense) continues to show that the dual status of EC and the unprecedented restrictions placed on it to enforce that dual status, place significant barriers in the path of all women seeking EC, severely undermining the very purpose of OTC access. What is most clear, however, is that efforts to make emergency contraception available OTC and unrestricted have not and will never be considered by the FDA in a fair, scientifically-based manner in accordance with general agency procedures. Remand has only confirmed that political factors will never allow the expertise of the FDA scientists to carry the day; that the health and futures of women of all ages will continue to be sacrificed to further political goals unless this Court steps in to effectuate the scientific conclusions of the FDA scientists.

For these reasons, Plaintiffs submit that under the relevant standards, the proper relief for the FDA's continuous bad faith and arbitrary and capricious actions and decision-making upon remand—regarding both the Citizen Petition and the Plan B One-Step OTC SNDA (the FDA's proposed way to comply with the Court Order)—is as follows: an order directing Defendants to permit, within 30 days, the drug sponsors of Plan B One-Step, Plan B, Next Choice, Perrigo R and D's Levonorgestrel Tablets, and any drug eligible for filing an abbreviated new drug application because of its equivalence to Plan B or Plan B One-Step, to make the above-referenced products available over-the-counter without age or point of sale restrictions. Given the harms that the FDA's bad faith tactics have imposed upon women for over ten years, Plaintiffs respectfully request that this Court issue such an order immediately.

CONCLUSION

For all the foregoing reasons, and to restore the scientific integrity of the FDA's drug evaluation process, this Court should enter judgment for Plaintiffs on the cause of action pled in the Supplemental Complaint and issue both a preliminary injunction and a permanent injunction directing Defendants to permit, within 30 days, the drug sponsors of Plan B One-Step, Plan B, Next Choice, Perrigo R and D's Levonorgestrel Tablets, and any drug eligible for filing an abbreviated new drug application because of its equivalence to Plan B or Plan B One-Step, to make the above-referenced products available over-the-counter without age or point of sale restrictions.

Dated: February 8, 2012

Respectfully submitted,

/s/ *Suzanne Novak*
SUZANNE NOVAK
JANET CREPPS*
Center for Reproductive Rights
120 Wall Street, 14th Floor

New York, NY 10005
(917) 637-3600

Attorneys for all Plaintiffs

ANDREA COSTELLO*
Florida Institutional Legal Services
14260 W. Newberry Road, #412
Newberry, FL 32669
(352) 375-2494 x1012

Attorneys for Plaintiffs
Tummino, Mahoney, Giardina,
Mangan, Seguin, Tinney, Brown
Churchill and Hunt

**Admitted pro hac vice*